IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Thomas W. Leonard

Application No.: 10/821,278 Filed: April 8, 2004

Confirmation No.: 1153 Group Art Unit No.: 1617

Examiner: Sahar Javanmard

METHODS OF ADMINISTERING ESTROGENS AND PROGESTINS

Date: June 2, 2009

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

SUBMISSION OF TERMINAL DISCLAIMERS UNDER 37 C.F.R. § 1.321(b)

Sir:

Applicants hereby submit the enclosed Terminal Disclaimers Under 37 C.F.R. § 1.321 in order to overcome the double patenting rejection for the above referenced application. Applicants have simultaneously filed a Notice of Appeal directed to the 35 U.S.C. §103 rejection of Claims 10-16, 19-23, and 29. The Examiner is authorized to charge Deposit Account No. 50-0220 the amount of \$280.00 [37 C.F.R. § 1.20(d)] to cover the fee for filing two Terminal Disclaimers. The Examiner is authorized to charge Deposit Account No. 50-0220 for any additional fee which may be required or credit any overpayment.

Respectfully submitted,

F. Mighael Sajovec Registration No. 31,793

USPTO Customer No. 20792 Myers Bigel Sibley & Sajovec Post Office Box 37428 Raleigh, North Carolina 27627 Telephone: 919/854-1400

Facsimile: 919/854-1401

CERTIFICATION OF TRANSMISSION

I hereby certify that this correspondence is being transmitted via the Office electronic filing system in accordance with § 1.6(a)(4) to the/U.S. Patent and Trademark Office on June 2, 2009.

Betty-Lou Rossert

Confirmation No.: 1153

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TERMINAL DISCLAIMER UNDER 37 C.F.R. 1.321(a)

Sir/Madam:

I, F. Michael Sajovec, am an attorney of record of the disclaimant, Barr Laboratories, Inc., and am authorized to execute this disclaimer on behalf of Barr Laboratories, Inc. The disclaimant, Barr Laboratories, Inc., having a principal place of business at 400 Chestnut Ridge Road, Woodcliff Lake, New Jersey, is the owner of all right, title, and interest in the above-identified application.

The disclaimant hereby disclaims, except as provided below, the terminal part of any patent granted on the above-identified application that would extend beyond the expiration date of the full statutory term as defined in 35 U.S.C. §§154 - 156, §173, and any other relevant statutory provision of prior U.S. Patent No. 7,427,609 B2, filed October 3, 2003, as presently shortened by any terminal disclaimer.

Disclaimant further agrees that any patent so granted on the above-identified application, which is the subject of this disclaimer, shall be enforceable only for and during such period that U.S. Patent No. 7,427,609 B2 and the instant application are commonly owned. This agreement runs with any patent granted on the above-identified application, and is binding upon the grantee, its successors, or assigns.

Nothing herein shall be construed as a disclaimer of any terminal part of any patent granted on the above-identified application that is prior to the expiration date of the full statutory term as defined in 35 U.S.C. §§154 - 156 and §173 of U.S. Patent No. 7,427,609 B2, as presently shortened by any terminal disclaimer, in the event that it later: expires for

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Filed: April 8, 2004

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failure to pay a maintenance fee, is held unenforceable, is found invalid by a court of competent jurisdiction, is statutorily disclaimed in whole or terminally disclaimed under 37 CFR §1.321, has all claims canceled by a reexamination certificate, is reissued, or is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer.

Respectfully submitted,

F. Michael Sajovec Registration No. 31,793

Myers Bigel Sibley & Sajovec, P.A.

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§ 1.6(a)(4) to the U.S. Patent and Trademark Office on June 2, 2009.

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Date: June 2, 2009

Mail Stop Amendment Commissioner of Patents P.O. Box 1450 Alexandria, VA 22313-1450

TERMINAL DISCLAIMER UNDER 37 C.F.R. 1.321

Sir:

I, F. Michael Sajovec, am an attorney of record of the disclaimant, Barr Laboratories, Inc., and am authorized to execute this disclaimer on behalf of Barr Laboratories, Inc. The disclaimant, Barr Laboratories, Inc., having a principal place of business at 400 Chestnut Ridge Road, Woodcliff Lake, New Jersey, is the owner of all right, title, and interest in the above-identified application, as evidenced by an Assignment recorded at the United States Patent and Trademark Office ("USPTO") on November 4, 2008, at Reel 021784, Frame 0118.

The disclaimant hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the above-identified application that would extend beyond the expiration date of the full statutory term as defined in 35 U.S.C. §§154 - 156, §173, and any other relevant statutory provision of prior U.S. Application No. 10/356,242, as presently shortened by any terminal disclaimer.

Disclaimant further agrees that any patent so granted on the above-identified application, which is the subject of this disclaimer, shall be enforceable only for and during such period that the patent granted on the above-identified patent application and United States Application Serial No. 10/356,242, is commonly owned. This agreement runs with any patent granted on the above-identified application, and is binding upon the grantee, its successors, or assigns.

Nothing herein shall be construed as a disclaimer of any terminal part of any patent granted on the above-identified application that is prior to the expiration date of the full

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Page 2

statutory term as defined in 35 U.S.C. §§154 - 156 and §173 of prior United States Application Serial No. 10/356,242, as presently shortened by any terminal disclaimer, in the event that one or more of the prior patents later: expires for failure to pay a maintenance fee, is held unenforceable, is found invalid by a court of competent jurisdiction, is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321, has all claims canceled by a reexamination certificate, is reissued, or is in any manner terminated prior to the expiration of its statutory term as presently shortened by any terminal disclaimer.

Respectfully submitted,

F. Michael Sajovec Registration No. 31,793

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June 2, 2009.

Betty-Low Rosser

page of Signature: June 2, 2009